

APPLICANTS: Cohen andamp;amp;path
U.S.S.N.: 08/851,628

REMARKS

Upon entry of the foregoing amendments, claims 1-4, 6-10, 12, 15-17, 24, 28, and 32-34 are pending in the present application.

The present Preliminary Amendment is filed to enter the amendments proposed in the November 12, 1999 After Final Amendment and Response, and to address some of the comments in the December 13, 1999 Advisory Action. Briefly, claims 1 and 2 have been amended to incorporate limitations of claims 13 and 14 that are *non-immune, non-inflammatory conditions*. Applicants have also amended claims 3 and 4 to more clearly define that the polypeptides of the present invention consist of at least the C-terminal *seven* cysteine domain. Support for this amendment can be found at pg. 5, line 18 through pg. 6, line 3; pg. 8, lines 4-16; pg. 13, line 4 through pg. 15, line 3; and pg. 16, lines 1-15. Finally, Applicants have amended claims 3 and 12 to recite the specific osteogenic proteins and bone morphogenic proteins known in the art at the time of filing of the present patent application. New claims 33 and 34 are drawn to one preferred embodiment. Support for these amendment and new claims is found at pg. 14, line 22 through pg. 15, line 3 and pg. 16, lines 1-21. No new matter has been added by the present amendments.

THE 35 U.S.C. §112, SECOND PARAGRAPH REJECTIONS

Claims 3, 4, and 12 remained rejected under 35 U.S.C. §112, second paragraph. In the Advisory Action, the Examiner stated that Applicants' Response of November 12, 1999 would overcome this rejection if the proposed amendments were entered. See, December 13, 1999 Advisory Action, page 2, first paragraph.

The present Preliminary Amendment is filed to enter the amendments proposed in the November 12, 1999 After Final Amendment and Response. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejections under 35 U.S.C. § 112, second paragraph.

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THE 35 U.S.C. §103(a) REJECTION

Claims 1-4, 6-10, 12-17, 24, 28, and 32 remain rejected under 35 U.S.C. §103(a) as being unpatentably obvious over **Glasscock** (V), and **Brenner** (U) in view of **Kuberasampath** (BB). The Examiner stated in the December 13, 1999 Advisory Action that Applicants' arguments have been fully considered but were not found to be persuasive because "the claims are not limited to treating chronic renal failure caused by non-immune, non-inflammatory conditions." The Examiner further stated that "All that the claims require is administering an OP/BMP renal therapeutic agent to a mammal in, or at risk of, chronic renal failure..."

Applicants strongly disagree. The claims as amended in the November 12, 1999 After Final Amendment and Response, and as amended herein¹ clearly require that:

... said mammal is afflicted with a condition selected from the group consisting of chronic diabetic nephropathy, diabetic glomerulopathy, diabetic renal hypertrophy, hypertensive nephrosclerosis, hypertensive glomerulosclerosis, renal dysplasia, glomerular hypertrophy, tubular hypertrophy, glomerulosclerosis and tubulointerstitial sclerosis ...

As explained in the November 12, 1999 After Final Amendment and Response, a skilled artisan would not use an anti-inflammatory therapy to treat chronic renal failure cause by **non-immune, non-inflammatory** conditions such as chronic diabetic nephropathy, diabetic glomerulopathy, diabetic renal hypertrophy, hypertensive nephrosclerosis, hypertensive glomerulosclerosis, renal dysplasia, glomerular hypertrophy, tubular hypertrophy, glomerulosclerosis and tubulointerstitial sclerosis. Accordingly, Applicants request reconsideration and withdrawal of this rejection under 35 U.S.C. §103(a).

¹ Applicants note that the pending claims are amended in order to expedite allowance of the present application, without prejudice to the prosecution of claims of similar or greater scope in this or a subsequent related application. Applicants respectfully submit again that, for the reasons provided in the May 6, 1997 Amendment and Response, the Examiner has failed to establish the required *prima facie* case of obviousness because (i) the cited references fail to provide the suggestion or motivation to modify the reference or to combine reference teachings; (ii) the cited references fail to provide a reasonable expectation of success; and (iii) the cited references fail teach or suggest all the claim limitations.

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CONCLUSION

On the basis of the foregoing amendments and remarks, Applicants respectfully submit that the pending claims are in condition for allowance. If there are any questions regarding these amendments and remarks, the Examiner is encouraged to contact the undersigned at the telephone number provided below.

Respectfully submitted,



Dated: February 11, 2000

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